Exhibit 3

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Alliance for Hippocratic Medicine, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendant.	Case No. 2:22-cv-00223-Z

DECLARATION OF LUU IRELAND, MD, MPH, FACOG

I, Luu Ireland, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury that the following is true and correct to the best of my knowledge and belief, and that these statements are based on my personal knowledge as well as information made known to me in the course of my medical practice:

1. I am a board-certified Obstetrician-Gynecologist ("Ob-Gyn") physician and attending physician at the University of Massachusetts Memorial Health in Worcester, Massachusetts. At UMass Memorial Health, I serve as an Assistant Professor of Obstetrics and Gynecology and Departmental Director of Diversity, Equity and Inclusion. I also serve as a staff physician for Planned Parenthood League of Massachusetts. I am board-certified in both Obstetrics and Gynecology and Complex Family Planning. In my day-to-day practice, I provide full-spectrum obstetric and gynecologic care. In my gynecologic role, I provide routine annual exams, contraceptive counseling for pregnancy prevention, treatment for a range of gynecological issues including abnormal uterine bleeding, management of abnormal pap smears, treatment of uterine fibroids and vulvovaginal disorders, and routine gynecologic surgery. In my obstetric role, I

participate in both inpatient and outpatient management of pregnancies, including prenatal care, labor and delivery, and postpartum care. This includes diagnosis and treatment of pregnancy complications and pregnancy loss. I also provide family planning services through Planned Parenthood League of Massachusetts. Approximately 30% of my clinical time is spent providing abortion-related care.

2. I earned my masters degree from the Mailman School of Public Health at Columbia University in New York in 2005. I graduated with a medical doctorate from the David Geffen School of Medicine at the University of California, Los Angeles (UCLA) in 2009 and completed my residency in Obstetrics and Gynecology at Women and Infants Hospital of Rhode Island/Warren Alpert School of Medicine at Brown University in 2013. I completed fellowship training in Complex Family Planning at UCLA in 2015. I joined the faculty of UMass Memorial Health in 2015 where I continue to serve as a clinician, educator, and leader to the department of Obstetrics and Gynecology.

3. In my current position, I have been active in undergraduate and graduate medical education for medical students, residents, and undergraduates. For medical students, I provide both didactic education during the 2nd year Reproductive Health Curriculum and clinical education during the 3rd year clerkship rotation and 4th sub-internship rotations and electives. I also serve as a Longitudinal Preceptor to provide clinical experience and teaching to 4 assigned medical students per year during their 1st and 2nd years of medical school. I am also a Faculty Advisor for the Women's Health Elective, a student run curriculum covering the public health aspects of reproductive health care. Finally, for 5 years, I served as a Learning Communities mentor in which I provided mentorship, support, and guidance to 6 to 12 medical students per year. Within this role, I taught physical exam techniques, history taking, medical documentation, and oral presentations.

For resident trainees, I support this educational process in a number of ways. In the clinic, I precept residents in performing outpatient prenatal, postpartum, and gynecologic care. In the operating room, I teach and supervise residents in a variety of gynecologic surgeries. On Labor and Delivery, I teach and supervise residents in the management of labor, pregnancy and postpartum complications, vaginal deliveries, and cesarean sections. As a Complex Family Planning specialist, I educate residents on the clinical considerations around contraception, abortion, and management of pregnancy loss. I teach residents how to provide patient-centered counseling around pregnancy prevention, termination, and miscarriage. I teach them how to perform medical and surgical care for abortion and pregnancy loss. This education takes place in the office, the operating room, Labor and Delivery, and at Planned Parenthood. My commitment to education goes beyond clinical teaching. I have also served as a research mentor to resident physicians and this work has resulted in several presentations at academic conferences. I have received several awards for my teaching, including the UMass Golden Apple awards, UMass Medical School Outstanding Medical Educator Award, and the Council on Resident Education in Obstetrics and Gynecology National Faculty Award for Excellence in Residency Education.

I have published book chapters on pregnancy loss in the first trimester[i], as well as Combined Oral Contraception[ii]. I also published a review article on pain control for outpatient gynecologic procedures[iii]. As a researcher, I have peer-reviewed publications on long-acting reversible contraception[iv], efficacy of medical and surgical abortion in the first trimester[v], and guidelines on preventive health care for women.[vi]

Leadership is a significant part of my role as a physician. Within the department, I serve as the Director of Diversity, Equity, and Inclusion (DEI). I lead initiatives to improve pregnancy related outcomes among Black and Latinx pregnant patients. I organize educational sessions for faculty

and residents on DEI related topics. I also serve as a statewide and national leader in reproductive health care. I am the current Chair of the Massachusetts section of the American College of Obstetricians and Gynecologists (ACOG). I also serve on the Committee for Maternal and Perinatal Welfare for the Massachusetts Medical Society. I am an active board member for the Planned Parenthood Advocacy Fund. On the national level of ACOG, I serve on both the Committee for Clinical Practice Guidelines in Gynecology as well as the Abortion Access and Expert Working Group.

In sum, I have been a practicing Obstetrician and Gynecologist for 14 years and in this time, I have cared for thousands of women. I have used this experience to educate and mentor the next generation of physicians and lead my field in the practice of evidence-based medicine. The health and well-being of women is my first and foremost goal and career mission.

4. I am a certified prescriber of Mifepristone under the REMS Program, have used it in the course of my practice, and continue to rely on the medication to ensure the best outcomes for my patients. Mifepristone is well known as part of the evidence-based regimen for medication abortion in the first trimester. Complications are exceedingly rare—both nationally and in my patient population—but include incomplete abortion or retained products of conception, excessive bleeding, or infection, which can be quickly resolved, typically with a surgical aspiration procedure. These extremely low risks are much lower than the risk of complications in carrying a pregnancy to term.

5. Suction dilation and curettage (D&C) is a form of surgical abortion and is a safe procedure that occurs in the first trimester (13 weeks gestation or less) to evacuate the uterus and remove products of conception. The pregnant person is placed in the same position as she would be for a pelvic exam. A speculum is placed in the vagina so that the cervix, or the opening of the uterus, is

visualized. A numbing medicine is injected around the cervix. The opening of the cervix is dilated until it can accommodate a plastic tube. Gentle suction is then used to empty the uterus. The whole procedure takes less than 5 minutes. In the second trimester (14 to 24 weeks), the procedure is known as a dilation and evacuation (D&E). The difference in this procedure is that pre-procedural medications or dilators are often needed to open the cervix to ensure patient safety. Additional instruments beyond suction may be needed to remove the pregnancy. These procedures can be performed in the office setting or in the operating room under sedation or general anesthesia, determined by patient preference. Complications are also exceedingly rare but can include heavy bleeding or hemorrhage, infection, retained products of conception, retained blood clots in the uterus, or uterine perforation. In my experience, these occur less than 1% of the time in first trimester cases and 1-2% of the time in the second trimester (risk increases with gestational age). These risks are much lower than the risk of complications in carrying a pregnancy to term.

6. Medical management of first trimester abortion is completed with a combination of Mifepristone and Misoprostol. Mifepristone (200mg) is a progesterone receptor antagonist, meaning it blocks and deactivates the receptor for progesterone, which is essential to support the pregnancy in the first trimester. In my judgment, there is also evidence that Mifepristone weakens the attachment of the pregnancy to the wall of the uterus and softens the cervix. Misoprostol (800mcg) is administered next and this causes uterine contractions and expulsion of the products of conception. In my practice, Mifepristone is given orally, in the office. For medication abortion, for which Mifepristone has FDA-approval, Misoprostol is administered within 0 to 48 hours following Mifepristone.

7. I have found that patients often prefer a medication management for abortion for various reasons, including the sense that it feels like a more "natural" process and the preference to avoid

surgery or anesthesia. Some patients have uterine anomalies such as large fibroids which make uterine evacuation by suction D&C challenging. There are also particular patient populations for which medical management is more appropriate. This includes patients who are survivors of abuse, including rape and incest, for whom pelvic exams can recreate severe trauma. Adolescent patients, who have not yet had a pelvic exam, frequently prefer medical management as a less invasive option. Finally, patients in the intensive care unit or trauma patients who have difficulty with the positioning required for suction D&C can benefit from medical management.

8. Prior to prescribing mifepristone, legal and medical ethics require providers, such as myself, to ensure that appropriate informed consent is obtained and that shared decision-making is effectuated by the patient and her family members, if she chooses. In ensuring that patients are fully informed when choosing among options for an unplanned or undesired pregnancy, I review all options including continuing the pregnancy to its natural conclusion and choosing parenting or adoption, and pregnancy termination via medical or surgical abortion. Once a patient chooses abortion, I review the risks and benefits of each modality. I usually explain that both medication and surgical abortion are safe, effective, and have no bearing on future fertility or risk of pregnancy complications. I describe how some patients choose medication abortion based on a preference to avoid a procedure and desire for a more "natural process" at home. I review that this process is more prolonged and can take hours to days to complete. I explain that follow-up is essential to ensure that the abortion is complete. I provide the patient with the Mifepristone Medication Guide and Patient Agreement, answer any questions, and ensure that the patient signs the Patient Agreement.

The process for medication abortion is as follows. A 200mg Mifepristone tablet is given in the office. This medication prepares the body to pass the pregnancy but does not work alone.

Misoprostol comes in 4 small tablets (200 mcg each) that need to be self-administered within 0 to 48 hours. Bleeding will occur within a few hours of Misoprostol administration. The bleeding can be heavy, with clots, and the cramping can be strong. In my experience, the vast majority of pregnancies will pass within 6 hours, after which the bleeding and cramping will get lighter and more closely resemble a menstrual period. The regimen has expected side effects that typically accompany the emptying of the patient's uterus, and these include fever, chills, nausea, vomiting, and diarrhea; these anticipated side effects are not considered complications and should resolve within 24 hours. Signs of complications include side effects that persist beyond 24 hours, bleeding in which the patient is completely saturating 2 maxi-pads per hour for 2 hours in a row, or severe pain that is worsening and unimproved with over-the-counter pain medications. Follow-up is required to ensure the pregnancy has completely passed, as there is a 1-4% percent chance of ongoing pregnancy depending on gestational age at time of abortion. As noted above, these complications can occur but, in my experience, do so very rarely.

Some patients prefer a surgical procedure due to the more predictable timeline to complete the abortion and the reduced need for follow-up. Some of these patients desire anesthesia during their abortion or prefer to avoid the heavy bleeding and cramping that can come with medication abortion. Some patients have contraindications to medication abortion including severe anemia, bleeding disorders, or inability to complete follow-up. When patients choose surgical abortion, I describe the procedure as well as the risks. For a suction D&C surgical abortion in the first trimester, the risk of a major complication C is less than 1% and these risks include severe pain, hemorrhage, infection, retained products of conception, retained blood clots in the uterus, or uterine perforation.

9. The information I provide to my patients is based on my years of training and experience both teaching new doctors and treating patients. I understand that use of all medications and medical procedures carry risks, including rare adverse events, and convey that understanding to patients as part of my regular medical practice. However, the use of Mifepristone has been tested clinically and used widely, with exceedingly low risks of side effects or adverse events. In my clinical practice, the benefits of Mifepristone far outweigh any potential risks.

10. As an example of the use of Mifepristone for my patients, I'd like to share my experience in caring for a 14-year-old girl who came to me with a 7-week pregnancy as a result of rape. She had the support of her mother, who was working with law enforcement to bring charges against her perpetrator. She strongly desired an abortion and to return to her normal ninth grade life. A surgical procedure to end the pregnancy would have been devastating and traumatic given her young age, lack of consensual sexual experience, and this very recent history of sexual trauma. She was so relieved to learn that we could offer her an abortion using pills alone. She went on to have an uncomplicated abortion at home with the support of her mother.

11. Another patient I cared for recently was a mother of six children who came to me with a 9-week unplanned pregnancy. She had been using the birth control patch, but due to a delay in changing her patch, she became pregnant. Her husband was in and out of her life, and did not reliably provide financial, social, or parenting support. She had 5 children living with her in a 2-bedroom apartment and was struggling to make ends meet. She could not conceive of how she would care for another child and adoption was not a choice that felt right for her. Because she was the sole and full-time parent for her children, ages 2 through 22, she could not take the time away from home, and arrange childcare and transportation, in order to have a surgical abortion. A

medication abortion with Mifepristone and Misoprostol allowed her to end the pregnancy safely and effectively, while maintaining her ability to parent and care for her children.

12. Another patient I cared for spent 10 years with an abusive partner. She finally pulled herself out of the relationship and obtained a divorce. The day the divorce was finalized, she found out she was pregnant. She was 8-weeks along when I met her. Knowing how unhealthy this relationship had been, and how long it took her to break free, she was confident that continuing the pregnancy would forever link her to her abuser. She strongly desired to end the pregnancy within the privacy of her own home. After 10 years of being in a relationship in which she had no power to make her own decisions, this was one of the first opportunities she had in a decade to make a choice for her own body.

13. I cared for another patient who had spent the last year recovering from severe postpartum depression and anxiety. This experience had rendered her unable to return to work and barely able to take care of her family. She had finally found a regimen of medications and therapy that was working to treat her crippling anxiety and panic attacks. She had finally decided on a return-to-work date. She finally had hope again. At the same time, she found out she was unexpectedly pregnant again. Upon learning she was 5-weeks pregnant, she sat in my office in tears thinking about reliving the same postpartum nightmare. She was also panicked about the idea of surgery and anesthesia. Knowing how severe and resistant her anxiety was, and observing her panic at the thought of surgery, I was grateful to offer her the option of medication abortion. She was relieved when she learned she had an option to end the pregnancy at home with the support of her husband nearby. She underwent an uncomplicated medication abortion at home. She became a long-term patient of mine, and each year, I get the honor of seeing her thrive as a mother, wife, and working individual.

14. I understand that Plaintiffs in this suit have asked the Court to revoke FDA's approval of Mifepristone. In my opinion, granting that request would cause substantial harm to patients and the medical practice because Mifepristone is safe. There are very few contraindications to the medication. Moreover, the drug has an excellent safety profile, with only exceedingly rare adverse events, and a very mild side effect profile.

Without Mifepristone, more patients will be forced to rely on surgical management for their abortions or forced to carry an unwanted pregnancy to term. Should the request to remove FDA approval of Mifepristone be granted, we would be eliminating a safe and effective treatment option for early abortion. To deny an evidence-based, safe and effective treatment goes against every part of my medical training and our profession's commitment to providing patient-centered care. Eliminating access to Mifepristone would unequivocally and unquestionably cause harm to patients without *any* clinical benefit. It would force patients into situations in which their autonomy for care is limited. I would no longer be able to explain that surgical and medical management of abortion are substantially equal in efficacy and risk. And this would coerce patients into having surgery that many are desperate to avoid, or facing the risks attendant to continuing pregnancy and childbirth against their own wishes.

There is also a large, negative public health impact should FDA approval of Mifepristone be revoked. Health care has never been in bigger crisis. Three years into the pandemic, COVID remains a leading reason for hospitalization. Health care workers have left the workforce in droves and medical facilities and hospitals are facing unprecedented issues in short staffing. Clinician burnout is a major issue and physician and nursing shortages are only expected to worsen. With this in mind, any increase in demand for limited resources available in the clinic or Operating Room is highly problematic. And this increase is guaranteed should Mifepristone be made

unavailable. More patients choosing surgical abortion will invariably lead to increased demand on resources for procedures in both the office and the operating room.

Dated January 13, 2023

Luu Ireland, MD, MPH, FACOG

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